



PATENT  
Customer No. 22,852  
Attorney Docket No. 02481.1707-01

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: )  
)  
Bernward SCHÖLKENS et al. ) Group Art Unit: 1614  
)  
Application No.: 10/694,001 ) Examiner: R. Henley, III  
)  
Filed: October 28, 2003 ) Confirmation No.: 3677  
)  
For: USE OF INHIBITORS OF THE )  
RENIN-ANGIOTENSIN SYSTEM )  
IN THE PREVENTION OF )  
CARDIOVASCULAR EVENTS )

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

**SUPPLEMENTAL INFORMATION DISCLOSURE**  
**STATEMENT UNDER 37 C.F.R. § 1.97(c)**

Pursuant to 37 C.F.R. §§ 1.56 and 1.97(c), Applicants bring to the attention of the Examiner the documents on the attached listing. This Supplemental Information Disclosure Statement is being filed after the events recited in Section 1.97(b) but, to the undersigned's knowledge, before the mailing date of either a Final action, Quayle action, or a Notice of Allowance. Under the provisions of 37 C.F.R. § 1.97(c), this Information Disclosure Statement is accompanied by a fee of \$180.00 as specified by Section 1.17(p).

Copies of the listed foreign and non-patent literature documents are attached. Copies of the U.S. patent publications are not enclosed.

Applicants respectfully request that the Examiner consider the listed documents and indicate that they were considered by making appropriate notations on the attached form.

Applicants enclose English language abstracts of DE 4308504 and DE 199 13 528 A1. With respect to the non-English language documents M.I. Balabolkin, "Endocrinology," Universum Publishing, pp. 390-391, 1998, and V.I. Metelitsa, "Handbook on Clinical Pharmacology of Cardiovascular Medicaments," Medpraktika, 1996, pp. 619 and 272, English translations of text in those documents are enclosed.

This submission does not represent that a search has been made or that no better art exists and does not constitute an admission that each or all of the listed documents are material or constitute "prior art." If the Examiner applies any of the documents as prior art against any claims in the application and Applicants determine that the cited documents do not constitute "prior art" under United States law, Applicants reserve the right to present to the office the relevant facts and law regarding the appropriate status of such documents.


Applicants further reserve the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should one or more of the documents be applied against the claims of the present application.

If there is any fee due in connection with the filing of this Statement, please charge the fee to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,  
GARRETT & DUNNER, L.L.P.

Dated: August 19, 2005

By:   
Steven J. Scott  
Reg. No. 43,911

US Form PTO/SB/08: Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet 1 of 2

**Complete if Known**

Application Number	10/694,001
Filing Date	October 28, 2003
First Named Inventor	Bernward SCHÖLKENS
Art Unit	1614
Examiner Name	R. Henley, III
Attorney Docket Number	02481.1707-01

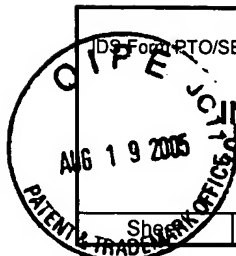
OIPE  
 AUG 19 2005  
 PATENT & TRADEMARK OFFICE

U.S. PATENTS AND PUBLISHED U.S. PATENT APPLICATIONS					
Examiner Initials	Cite No. <sup>1</sup>	Document Number	Issue or Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
		5,266,583	11/1993	Ohtawa	
		5,308,846	05/1994	Allen et al.	
		5,656,603	08/1997	Simmons	
		2005/0101658 A1	05/2005	Scholken et al.	

**Note: Submission of copies of U.S. Patents and published U.S. Patent Applications is not required.**

FOREIGN PATENT DOCUMENTS						
Examiner Initials	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	Translation <sup>6</sup>
		Country Code <sup>3</sup> Number <sup>4</sup> Kind Code <sup>5</sup> (if known)				
		GB 2 308 064	06/1997			
		DE 4308504	09/1994			
		DE 199 13 528 A1	06/2000			
		EP 0 241 201	10/1987			
		EP 0 540 209	05/1993			
		EP 0 747 050	12/1996			
		WO 97/27745	08/1997			
		WO 97/49392	12/1997			
		WO 98/30216	07/1998			
		WO 99/44590	09/1999			
		WO 00/02543	01/2000			
		WO 00/71751	11/2000			
		WO 01/15674	03/2001			

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	Translation <sup>6</sup>
		English language Derwent Abstract of DE 4308504	
		English language Derwent Abstract of DE 199 13 528 A1	
		Copy of Office Action dated July 27, 2004, in application No. 09/645,556	
		Copy of Office Action dated November 3, 2004, in application No. 09/645,556	
		Copy of Office Action dated January 24, 2005, in application No. 09/645,556	
		Copy of Office Action dated February 24, 2005, in application No. 09/645,556	
		Copy of Office Action dated June 29, 2005, in application No. 09/645,556	
		M.I. Balabolkin, "Endocrinology," Universum Publishing, pp. 390-391, 1998, with English language translation of portion of text	

 DS Form PTO/SB/08: Substitute for form 1449A/PTO		<b>Complete if Known</b>	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> (Use as many sheets as necessary)		Application Number	10/694,001
		Filing Date	October 28, 2003
		First Named Inventor	Bernward SCHÖLKENS
		Art Unit	1614
		Examiner Name	R. Henley, III
		Attorney Docket Number	02481.1707-01
Sheet	2	of	2

NON PATENT LITERATURE DOCUMENTS			
		Mel Blumenthal, Treatment of Congestive Heart Failure, Experience With Fosinopril, American Journal of Hypertension, Ltd. 1997, vol. 10, No. 10, Part 2, pgs. S289-S298	
		Bussien et al., The effect of the converting enzyme inhibitor HOE-498 [ramipril] on the renin angiotensin system of normal volunteers. Naunyn-Schmiedeberg's Archives of Pharmacology, 1985, vol. 329, pages 63-69	
		Cashin-Hemphill et al., "Angiotensin-Converting Enzyme Inhibition as Antiatherosclerotic Therapy: No Answer Yet," Am. J. Cardiol., vol. 83, pp. 43-47 (1999)	
		Database WPI, Week 19944, Derwent Publications Ltd., London, GB, AN 199-520858, XP-002166044, Masuda Yoshinobu, Honda Yayoi, Minato Hisao: "Inhibitor of cerebral vasospasm"	
		Robert T. Eberhardt et al., Angiotensin II Receptor Blockade: An Innovative Approach to Cardiovascular Pharmacotherapy, J. Clin. Pharmacol 1993, 33:1023-1038, XP-001019614	
		FDA Orange Book Active Ingredient Detail Record Search, June 1998	
		The GISEN Group, "Randomised placebo-controlled trial of effect of ramipril on decline in glomerular filtration rate and risk of terminal renal failure in proteinuric, non-diabetic nephropathy," THE LANCET, Vol. 349, 1997, pp. 1857-1863	
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		Willa A. Hsueh, MD, "In diabetes, treat hidden heart disease," Cleveland Clinic Journal of Medicine, vol. 67, no. 11, pages 807-813, November 2000	
		Robert MKW Lee et al., Effects of perindopril on hypertension and stroke prevention in experimental animals, Can. J. Cardiol., vol. 10, no. Suppl. D, November 1994, pgs. 33D-36D, XP000998206	
		V.I. Metelitsa, "Handbook on Clinical Pharmacology of Cardiovascular Medicaments," Medpraktika, 1996, pp. 619 and 272, with English language translation of portion of text	
		Fumiaki Nakamura et al., Chronic Administration of Angiotensin II Receptor Antagonist, TCV-116, In Cardiomyopathic Hamsters, American Physiological Society, 1994, pgs. H2297-H2304, XP-001019610	
		Noriko Ogiku et al., Prophylactic Effect of Imidapril on Stroke in Stroke-Prone Spontaneously Hypertensive Rats; Stroke, (Feb 1993) 24 (2) 245-52, XP000997781	
		K. Parfitt, Martindale - The Complete Drug Reference - Thirty-second Edition, 1999, Pharmaceutical Press, London, U.K., XP-002176301, pp. 836, 865, 891, 899, 951 and 960	
		J.E.F. Reynolds, "Martindale The Extra Pharmacopoeia, 1996, Royal Pharmaceutical Society, London, XP002166043, pp. 863, 864, 899, 900, 940 and 941	
		Charles T. Stier, Jr., et al., Enalapril Prevents Stroke and Kidney Dysfunction in Salt-Loaded Stroke-Prone Spontaneously Hypertensive Rats; Hypertension (Dallas), vol. 13, no. 2, 1989, pgs. 115-121, XP000997775	
		Charles T. Stier, Jr. et al., Stroke Prevention by Losartan in Stroke-prone Spontaneously Hypertensive Rats, Journal of Hypertension 1993, 11 (suppl 3) 537-542, XP-00109687	
		P. Trenkwalder, "Effects of candesartan cilexetil on glucose homeostasis," Basic Res Cardiol, 93:Suppl. 2, pp. 140-144, 1998	
		Webb et al., Vascular Angiotensin Conversion in Humans, Journal of Cardiovascular Pharmacology, 8 (Suppl. 10), S40-S44, 1986	

Examiner Signature		Date Considered	
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EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.